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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,883	08/20/2001	Vaughn Vasil		4041

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EXAMINER	
PADMANABHAN, KARTIC	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,883	VASIL, VAUGHN	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-12,14 and 16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-12,14 and 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/20/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/04 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5, 7, 12, 14, 17, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al. (US Pat. 5,919,626). The reference discloses the attachment of nucleic acids to solid surfaces, wherein an unmodified nucleic acid molecule is coupled to a silane-coated solid phase. The unmodified nucleic acid molecules may be genomic DNA or cDNA. The solid support of the reference may be a microtiter plate. The method of the reference may also comprise the step of capturing from a solution at least one strand of a specific polynucleotide analyte by hybridization to the immobilized nucleic acid molecule and detecting the captured analyte (claim 24 of reference). The analyte of the reference may also be protein.

4. Claims 1-2, 9, 12, 14, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (US Pat. 5,563,036). The reference discloses a method of screening for a

compound comprising the steps of forming a mixture by combining a labeled protein and a nucleic acid conjugate, wherein the compound and a receptor are immobilized on a solid substrate, and said conjugate comprises a nucleotide sequence and a ligand specific for the receptor. The receptor then binds ligand, and in the absence of the compound, the labeled protein is bound to the nucleic acid conjugate. The presence or absence of the label on the protein on the substrate is then detected. The nucleic acid may be DNA or RNA. The solid phase of the reference may be a bead or microtiter plate. Exemplary ligand receptor pairs include antigen and antibody.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 10-11 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (US Pat. 5,563,036). The references teach screening assays, as previously discussed. However, the references do not teach DNA-PK or anti-DNA-PK antibody.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect DNA-PK and use anti-DNA-PK antibodies for this purpose because the selection of the analyte of interest merely represents an optimization of the assay protocol. Depending on the analyte of interest chosen, one of skill in the art would have known the appropriate antibody to use. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. Claims 4, 6, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi et al. (US Pat. 5,919,626) or Peterson et al. (US Pat. 5,563,036) in view of Yamane (US Pat. 5,741,638).

Shi et al. and Peterson et al. teach detection methods, as previously discussed. However, the references do not teach the use of damaged or UV-irradiated DNA.

Yamane teaches a microtiter well for detecting a nucleic acid. According to the reference, a single stranded nucleic acid that is specifically hybridizable with a target nucleic acid is immobilized on a microtiter well. Detection of the target analyte occurs after it contacts the immobilized single stranded nucleic acid. The immobilized nucleic acid may be DNA, and the DNA may be irradiated with UV to achieve immobilization (Example 4). When the label used for detection is indirectly detectable, detection of target analyte may be carried out by using an acceptor (such as via the use of an antibody).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use damaged DNA as taught by Yamane with the methods of Shi et al. or Peterson et al. because Peterson et al. state that any nucleic acid or analog may be used as long as

sequence specific binding is still possible. The DNA may also be of any length. As such, one would have had a reasonable expectation of success is using damaged DNA with the methods of Shi et al. or Peterson et al.

9. Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi et al. (US Pat. 5,919,626) or Peterson et al. (US Pat. 5,563,036) in view of Giordano et al. (US Pat. 5,705,344).

Shi et al. and Peterson et al. teach detection methods, as previously discussed. However, the references do not teach the detection of DNA repair proteins.

Giordano et al. teach screening assay for helicase inhibitors, wherein a mixture is formed of a first nucleic acid hybridized to an unlabeled second nucleic acid, a helicase, a nucleoside triphosphate, and a test agent. The first and second nucleic acids may both be DNA. The second nucleic acid is immobilized on a solid substrate, and the amount of label retained on the immobilized second nucleic acid is measured as an indication of helicase modulation (Claim 1). Helicases are enzymes that may function in various cellular functions, including DNA repair. The candidate helicase samples are typically cellular or nuclear extracts (Col. 7, lines 50-56). Detection may be carried out by coating the substrate with an antibody (claim 5 of reference).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to detect proteins involved in DNA repair as taught by Giordano et al. with the method of Shi et al. or Peterson et al. because the selection of the analyte of interest merely represents an optimization of the assay protocol. Depending on the analyte of interest chosen, one of skill in the art would have known the appropriate receptors to use. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its

suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

10. Applicant's arguments filed 6/21/04 have been fully considered and are persuasive to overcome Giordano et al. as a 102 reference, but they are not persuasive to overcome the other pending rejections.

11. Applicant argues that Shi does not anticipate the claims because the reference does not disclose DNA-structure specific binding protein assays. This is not convincing because Shi immobilizes predetermined DNA molecules to a solid surface. Since these structures are predetermined, this is interpreted to fall within the meaning of specific DNA structures for the reason that they are specifically chosen for use in the assay. Applicant also argues that Protein-DNA complex detection is not discussed in the reference. It is first noted that the claims only require that protein be detected. Further, the reference specifically states that the invention of the reference is useful in assays involving nucleic acids, as well as proteins. As such, the reference contemplates use of the immobilized oligonucleotides to bind protein as well and nucleic acid analytes, and provides the requisite guidance on doing this. The disclosure of the reference makes clear that protein analytes could be substituted for polynucleotide analyte, and the method of the reference would still work.

12. Applicant argues that the Peterson reference requires sequence-specific binding, and not structure specific; however, the sequence of a molecule is deemed to be a part of its structure. For example, the structure of a chemical compound consists of its shape, as well as the sequence of molecules that make up its chemical formula, which determines its 3-dimensional shape.

Although applicant may be correct in asserting that the detection methods will necessarily be different between Peterson and the present invention, the claims only generically refer to detection and do not recite a specific process of detection. Applicant also has not discussed the way in which Peterson and the claimed invention would differ in their detection techniques.

13. Applicant's arguments with respect to the 103 rejection of claims 10-11 and 21-22 over Peterson are not convincing for reasons discussed above with respect to the distinction between structure and sequence. Further, although DNA-PK does not bind DNA in a sequence specific manner, one could still have used DNA-PK as the antibody in the method of Peterson to detect binding.

14. Applicant's arguments with respect to the 103 rejection of claims 4, 6, 16, and 18 over Shi or Peterson in view of Yamane are also unconvincing. Applicant claims that anomalous results are likely if damaged DNA is used in the method of Peterson et al. but has not provided any basis for this position. The argument regarding differing detection means that may be required is moot, as specific detection means are not recited in the claims.

Conclusion

Claims 1-2, 4-12, 14, and 16-23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

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LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/17/04